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AL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT

01662/53002

Application of: M. Fleshner-Barak et al.

Acation No.: 09/887,204

June 22, 2001

or: RAPIDLY EXPANDING COMPOSITION FOR GASTRIC RETENTION AND CONTROLLED RELEASE OF THERAPEUTIC AGENTS, AND DOSAGE FORMS INCLUDING THE COMPOSITION

The owner*, Teva Pharmaceutical Industries, Ltd., of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term prior patent No. 6,476,006 as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:

expires for failure to pay a maintenance fee; is held unenforceable;

is found invalid by a court of competent jurisdiction;

is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;

has all claims canceled by a reexamination certificate; is reissued; or

is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

For submissions on behalf of a business/organization (e.g., corporation, partnership, university, 1. ☑ government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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STATEMENT UNDER 37 CFR 3.73(b)

We hereby declare that Teva Pharmaceutical Industries, Ltd. is the assignee of the entire right, title, and interest in the patent identified above by virtue of an assignment from the inventor(s) of said patent executed on May 13, 2001. The assignment was recorded in the United States Patent and Trademark Office at

Reel 011894, Frame 0698.

Yehudah Livneh, PhD. Typed or printed name

Typed or printed name **Director of Patents**

97239267351

Telephone Number

General Counsel & Corporate Secretary

Terminal disclaimer fee under 37 CFR 1.20(d) included.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignce (owner).

Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

This collection of information is required by 37 CFR 1.321. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) and

Into concertion of information is required by 37 CFR 1.321. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOTE SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO. Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION

Docket Number (Optional) 01662/53002

Here Application of: M. Fleshner-Barak et al.

pplication No.: 09/887,204

Filed: June 22, 2001

For: RAPIDLY EXPANDING COMPOSITION FOR GASTRIC RETENTION AND CONTROLLED RELEASE OF THERAPEUTIC AGENTS, AND DOSAGE FORMS INCLUDING THE COMPOSITION

The owner*, Teva Pharmaceutical Industries, Ltd., of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending reference Application Number 10/420,403, filed on April 22, 2003, a continuation of U.S. Patent Application Serial No. 10/246,502, filed September 16, 2002, which is a continuation of U.S. Patent Application Serial No. 09/770,898, filed January 26, 2001, now U.S. Patent No. 6,476,006, as such term is defined in 35 U.S.C. 154 and 173, and as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the reference application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of any patent granted on said reference application, "as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application," in the event that: any such patent: granted on the pending reference application: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

Check either box 1 or 2 below, if appropriate.

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We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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STATEMENT UNDER 37 CFR 3.73(b)

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Jzi Karnie Typed or printed name

Signature Yehudah Livneh, PhD. Typed or printed name

3 926 7351 Telephone Number

Director of Patents

General Counsel & Corporate Secretary

☑ Terminal disclaimer fee under 37 CFR 1.20(d) included.

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION

In re Application of: M. Fleshner-Barak et al.

Application No.: 09/887,204

Filed: June 22, 2001

For: RAPIDLY EXPANDING COMPOSITION FOR GASTRIC RETENTION AND CONTROLLED RELEASE OF THERAPEUTIC AGENTS, AND DOSAGE FORMS INCLUDING THE COMPOSITION

The owner*, Teva Pharmaceutical Industries, Ltd., of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending reference Application Number 10/026,573, filed on December 20, 2001, as such term is defined in 35 U.S.C. 154 and 173, and as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the reference application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of any patent granted on said reference application, "as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application," in the event that: any such patent: granted on the pending reference application:

expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

Check either box 1 or 2 below, if appropriate.

For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

	The undersigned i	s an attorney	or agent of re-	cord. Reg.	No
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STATEMENT UNDER 37 CFR 3.73(b)

We hereby declare that Teva Pharmaceutical Industries, Ltd. is the assignee of the entire right, title, and interest in the patent application identified above by virtue of an assignment from the inventor(s) of said patent application executed on February 13, 2002. The assignment was recorded in the United States Patent and Trademark

Office at Reel 013032, Frame 0273.

Uzi Karniel

Signature Yehudah Livneh, PhD.

Typed or printed name

9723<u>92673</u>51 Telephone Number

Typed or printed name General Counsel & Corporate Secretary

Director of Patents

☑ Terminal disclaimer fee under 37 CFR 1.20(d) included.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

"Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assigned (owner).

Form PTO/SB/96 may be used for making this certification. See MPEP '324.

This collection of information is required by 37 CFR 1.321. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOTE SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING

Docket Number (Optional) 01662/53002

REJECTION OVER A PENDING "REFERENCE" APPLICATION

In re Application of: M. Fleshner-Barak et al.

Application No.: 09/887,204

Filed: June 22, 2001

For: RAPIDLY EXPANDING COMPOSITION FOR GASTRIC RETENTION AND CONTROLLED RELEASE OF THERAPEUTIC AGENTS, AND DOSAGE FORMS INCLUDING THE COMPOSITION

The owner*, Teva Pharmaceutical Industries, Ltd., of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending reference Application Number 10/196,766, filed on July 17, 2002, as such term is defined in 35 U.S.C. 154 and 173, and as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the reference application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

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STATEMENT UNDER 37 CFR 3.73(b)

We hereby declare that Teva Pharmaceutical Industries, Ltd. is the assignee of the entire right, title, and interest in the patent application identified above by virtue of an assignment from the inventor(s) of said patent application executed on November 4, 2002. The assignment was recorded in the United States Patent and Trademark Office at Reel 013692, Frame 0718.

Typed or printed name

General Counsel & Corporate Secretary

Yehudak Livneh, PhD.

Typed or printed name **Director of Patents**

39267351 Telephone Number

☑ Terminal disclaimer fee under 37 CFR 1.20(d) included.

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